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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/018,629      | 12/14/2002  | Curtis D. Pfeiffer   | 44557               | 5189             |

109 7590 06/10/2003

THE DOW CHEMICAL COMPANY  
INTELLECTUAL PROPERTY SECTION  
P. O. BOX 1967  
MIDLAND, MI 48641-1967

EXAMINER

LUDLOW, JAN M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1743

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DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/018,629

Applicant(s)

PFEIFFER ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Claims 1-16, 18 are objected to because of the following informalities: claims 1 and 9 have dark photocopy marks across the upper half, making claim reading and scanning for printing difficult. Claim 6 should depend from claim 2 to provide antecedence for step g. Claim 18 depends from cancelled claim 17. Appropriate correction is required.

2. Claims 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The composition of the second fraction in claim 9 is unclear—step G(1)c refers to methylation to produce esterified second fractions and step K refers to alkylated second fractions. Note that throughout the claims “biological material” has been interpreted to refer to both the subject and control biological materials.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-4, 6-8, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chappell et al.

Chappell teaches a method of comparing transgenic products to control products. Samples are extracted in alcohol/water with KOH added and subjected to GC analysis. Three fractions for root, callus and leaf are used, as shown by the data in Table 4, which also identifies peak differences between the transgenic sample and control, i.e., the instant "outlier" (cols. 3-4, Example 3). Chappell further teaches that isopropanol is a suitable extraction alcohol (col. 20, lines 23-24) and that positive identification of peaks by GC/MS may be performed (col. 27, line 31).

Chappell fails to explicitly teach that the method of example 3 uses isopropanol or GC/MS.

It would have been obvious to use isopropanol as the alcohol in the method of Chappell in order to use a suitable alcohol as taught by Chappell. It would have been further obvious to use GC/MS to identify the peaks in order to make positive

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identification of the chemical composition of the peaks as taught by Chappell. With respect to claims 3-4, it would have been obvious to perform the method steps in any logical order in order to perform the required steps for comparison as taught in that there is no criticality to the order of sample preparation and chromatographing between the control and transgenic sample. With respect to claim 7, it would have been obvious to use a computer for data analysis in order to automate calculation as was known in the art.

7. Claims 5 and 18/5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chappell as applied to claims 1-4, 6-8, 18 above, and further in view of Waggle et al.

Chappell fails to teach liquid chromatography of the sterol-containing extracts.

Waggle teaches that sterols in plant extracts can be further purified by HPLC (col. 6, lines 59-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use HPLC in place of GC in the invention of Chappell in order to further separate sterols in plant extracts by an alternative form of chromatography as taught by Waggle. Note that Waggle specifically cites as suitably separated 3 of the sterols found in Table 4 of Chappell.

8. Claims 9-16 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

The prior art fails to teach or suggest the method as claimed, including the production of the first, second and third fractions by the methods claimed from subject

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and control biological materials, chromatographing the fractions and comparing the chromatograms to determine chemically related differences.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Derwent Acc. No. 1994-107916 teaches extraction with isopropanol and water followed by liquid chromatography.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow  
Primary Examiner  
Art Unit 1743

jml  
June 8, 2003